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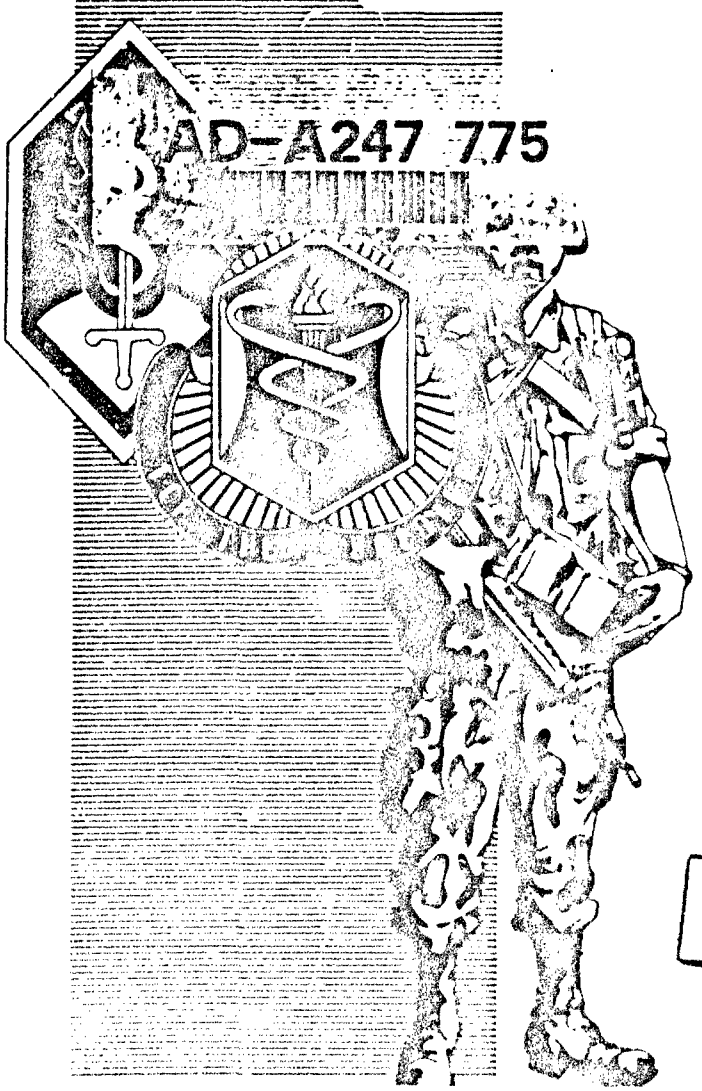
UNITED STATES ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY

U.S. ARMY

MEDICAL MATERIEL DEVELOPMENT ACTIVITY

1991 ANNUAL REPORT



FORT DETRICK, FREDERICK, MD 21702-5000

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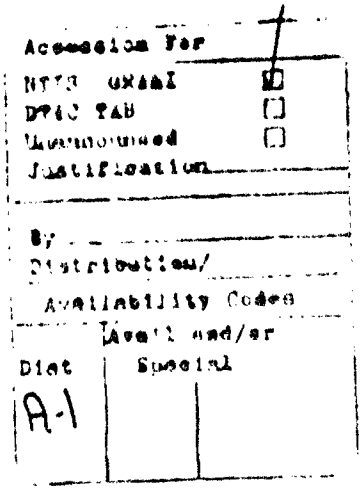

U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY
FORT DETRICK
FREDERICK, MARYLAND 21702-5009

31 JANUARY 1992

ANNUAL REPORT FOR PERIOD 1 JANUARY 1991 - 31 DECEMBER 1991

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
FORT DETRICK
FREDERICK, MARYLAND 21702-5012

N O T I C E

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The Annual Report, Calendar Year 1991, summarizes development projects monitored by the U.S. Army Medical Materiel Development Activity in projects authorized by The Surgeon General, the Army, and the Commander, U.S. Army Medical Research and Development Command, and supported by RDTE funds from the U.S. Army Medical Research and Development Command.

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U.S. ARMY
MEDICAL MATERIEL DEVELOPMENT ACTIVITY

1991 ANNUAL REPORT

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INTRODUCTION

This calendar year was perhaps the most exciting since the inception of the U.S. Army Medical Materiel Development Activity (USAMMDA) in 1985. As the Organization continued to mature in its medical materiel development role, we were confronted with the very real events in the Middle East as Operation Desert Shield became Desert Storm; and concomitant with the deployment of military personnel, the need for the products of medical research and development became even more relevant and immediate. Notable among the rapidly-fielded successes were the Convulsant Antidote for Nerve Agent (CANA) for CW protection, Botulism Antitoxin for BW protection and several lightweight materiel products originally protyped by the U.S. Army Biomedical Research and Development Laboratory (USABRDL). Several other products, such as Ballistic and Laser Eye Protection, Insect Arthropod Repellant Lotion, Mark I Nerve Agent Antidote Kit (NAAK) and Skin Decontaminating Kit (SDK), fully developed by the Command and fielded within the past few years, performed admirably, as intended. Even those products which were not as successful as expected provided us with invaluable "lessons learned" which will serve us well in the years ahead. All in all, we believe that our support to the troops served them well, and we are pledged to continue our efforts on their behalf.

Our major materiel effort for oxygen production in the theater (Field Medical Oxygen Generating and Distribution System (FMOGDS)) is now proceeding as planned toward a logical "shoot-off" with a Liquid Oxygen Production System early in 1992. Lessons learned from the development of the High Capacity X-ray System will provide a basis for the Army Medical Department (AMEDD) to make a well-advised decision, rather than one of confrontation, as in the past. The Resuscitative Fluids Production System (REFLUPS) development previously perturbed by cost overruns and schedule slippages is now on-track, and REFLUPS will be operationally evaluated in April 1992 at Fort Sam Houston.

We had the opportunity to spend a great deal of time (and effort) with GAO representatives evaluating our efforts in the Biological Defense Research Program (BDRP). Although we lost many sound scientific arguments supporting our approach to the problem, we have now honed that program to respond more directly to clearly-defined Department of Defense threat criteria. As always, our vaccine and pharmaceutical product development efforts provided us with exciting new scientific and management challenges throughout the year; several initiatives to more appropriately manage human trials of promising products have been proposed, and decisions on these should be forthcoming during

FY 1992. The Base Realignment and Closure Act will affect USABRDL as it moves towards closure. Fortunately for the AMEDD and the U.S. Army Medical Research and Development Command, the Field Medical Materiel Development Division (FMMDD), to include the Industrial Services and Technical Services Branches, will be assimilated into the USAMMDA early in CY 1992. The technical testing capability of the Command will soon be expanded and modernized as we move to establish this Activity as the technical testing focus for all Services' medical materiel acquisitions. Finally, with the press of multiple, major issues facing the AMEDD during the year, implementation of the single AMEDD Research, Development and Acquisition (RDA) concept was not effected. Hopefully, this issue will be resolved to the satisfaction of all participants in the foreseeable future.

As in the past, we continue to scrub our development program both to assure accountability of our management efforts and to reevaluate the priorities of our developmental products in light of ever-constrained resources and the rapidly-changing global environment. The realignment of nations and the reestablishment of governments dormant for decades will challenge planners as former adversaries reassess their strategic goals. During the turbulent years ahead, our support for the operational concepts of Airland Operations will continue unabated; however, our goal will continue to focus on the effective development of products needed by our Servicemen and women in the field who are charged with carrying out our national defense objectives. If we all do our best for them, we can only succeed in our endeavors.

CARL E. PEDERSEN, JR.
Colonel, MS
Commanding

PROGRAM MANAGEMENT

INTRODUCTION

The Project Management Support Division (PMSD) provides centralized program-wide administrative, financial, contractual, regulatory affairs and logistical support. Throughout 1991, PMSD emphasis was directed to enhancing the support provided to the Project Management Divisions and improving accountability for resources throughout the AMEDD materiel development spectrum.

MAJOR ACCOMPLISHMENTS

RESOURCES MANAGEMENT

- Automated Data Processing Support: The 3Com local area network (LAN) was upgraded to 3+Open, providing laser quality printing for all Macintoshes and Zeniths; data exchange both within USAMMDA and among USAMRDC facilities on post; and networkable software. Network software now on the LAN includes WordPerfect 5.1, WordPerfect Office, and Smarterm 340. Additional Macintosh IIs were procured to meet the expanding presentation graphics needs of the staff. Upgrading of laser printers has improved network printing. An increased need for portable computing capacity resulted in additional purchases of Compaq notebooks and Macintosh powerbooks. Connections to the post-wide Fiber-optic Data Distribution Interface (FDDI) were completed to increase speed of data exchange and query capabilities with computer systems both on and off post.

- General Analysis/Priority System (GAPS): Development was completed on an expansion of GAPS, an automated resource management tool designed to assist in planning and programming for the cost of product development, to operate interactively with MAMP database and software, thus, maintaining data integrity and providing a stable environment for software and data maintenance needed to support the MAMP conference, while significantly reducing extraneous data calls. An additional module to control assignment of Baseline Product List numbers, the unique number used to differentiate and track products, was also added.

- Major Support Contract: The PMSD is the Contracting Officer's Representative (COR) for a major support contract with Sherikon, Incorporated, to provide approximately 25 technical manyears annually to accomplish the Project Managers' documentation requirements. The contract objective of facilitating the timely and efficient execution of medical materiel development was met by providing preparation and assembly of support documentation required for coordinating development, production, procurement and fielding of

developmental medical products. USAMMDA awarded 70 tasks during the year to provide In-Progress Review (IPR) participant packages, either a System Concept or a Decision Coordinating Paper; 20 cost estimates; 40 various logistical support plans and documents, 4 acquisition strategy plans; 8 market investigations; 4 draft requirements documents for staffing; 3 safety assessment reports; 2 materiel fielding plans; and several other product-specific analyses and papers; as well as support for program-wide data collection and analysis efforts such as the General Analysis/Priority System and the Mission Area Materiel Plan. Both the cost estimates and logistical support plans are accomplished under single umbrella-type orders to reduce processing time and costs associated with order processing.

- Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP): The FY 1991 Medical RDA MAMP Conference (July 1991) performed product assessments for evaluating the USAMRDC RDA Program with respect to medical-related combat requirements. Representatives from USAMRDC, USAMMDA, USAMMA, OTSG, Air Force, Navy, AHS, and TRADOC schools evaluated 78 development products and formally assessed 63 products against 27 medical area capability issues (CI). The 63 assessed products were then matched to 14 medical-related Battlefield Development Plan (BDP) capability issues and 3 Army Capability Packages. Regional applicability and level of care/intervention were tied together in a new concept to determine relative value added for each of the assessed products. A "value-added quotient" was determined by factoring the value to a field commander of keeping troops on line through preventive efforts, returning them to duty or treating them in fixed facilities against the probability of a product's use in one of eight geographical regions. A relative ranking was obtained for each Project Management Division to assure validity of individual assessments. The "value-added quotient" was also used by the OTSG program managers when considering the relative rank of product affordability. Affordability has been a consideration in previous MAMP conferences; however, this was the first formal attempt to measure the impact of affordability on product ranking by considering both an affordability index and value to the field commander specifically.

- Program Development: USAMRDC experienced broad-based support for medical developments in outyear program guidance during the 94-99 Long Range Army Materiel Requirements Plan formulation process during the summer and fall based on prioritization schemes formulated at the MAMP. USAMMDA, as the agent for preparation and defense of the development portion of the USAMRDC program, was heavily committed to preparing impact statements and program analysis to support the AMEDD participants, as well as providing personnel

the AMEDD participants, as well as providing personnel throughout the leadership reviews. No reductions were imposed on the USAMRDC development program.

HUMAN RESOURCES

- Because of the hiring freeze imposed by DOD, and recognizing USAMMDA's non-direct health care mission, the unit carried a shortfall of civilian fills throughout the year. However, USAMMDA is correctly positioned to assume the additional requirements, authorizations and personnel added to the unit as a result of FY 1992 Base Realignment and Closure Act actions.

- USAMMDA was very honored to have one of its employees, Ms. Anne Twist, an Operations Research Analyst, selected to attend the Army Comptroller Program at Syracuse University. This prestigious selection will provide USAMRDC with the latest in fiscal theory and applications. Ms. Twist is the first AMEDD civilian selected for the program.

- USAMMDA Key Personnel:

Position	Name	Date
Commander	COL C.E. Pedersen, Jr.	1 Jan 91 to 31 Dec 91
PM/AMSPMD	COL B.A. Schiefer	1 Jan 91 to 17 May 91
	LTC J.M. Churchman (Acting)	18 May 91 to 31 Dec 91
PM/BSPMD	Dr. W.E. Brandt	1 Jan 91 to 31 Dec 91
PM/PSPMD	COL D.G. Harrington	1 Jan 91 to 31 Dec 91
Dir/PMSD	MAJ W.F. Heinemann	1 Jan 91 to 30 Sep 91
	Mr. W.R. Ferguson (Acting)	1 Oct 91 to 31 Dec 91

- USAMMDA Strength: As of 31 December 1991:

	Military	Civilian	Total
Required	25	51	76
Authorized	18	34	52
Actual	11	31	42

FISCAL PERFORMANCE

- **In-House**: USAMMDA in-house fiscal execution exceeded the established disbursement target for FY 1991. Though the obligation percentage was 0.5% below target, it was the smallest absolute carryover amount in USAMMDA's brief history. Disbursements for FY 1991 exceeded the target by almost 50% but still fell below FY 1990 performance by 8%, attributable mainly to a drop-off in support contractor billings.

	Allotment	Obligations	Disbursements
FY 1991 Dollars ($000)	3,795	3,776	2,742
Target (%)		100	51
Actual (%)		99.5	72.3

- **Program Wide**: Performance in the command-wide development program was not as successful as USAMMDA in-house, but more successful than FY 1990. Both laboratory and extramural program performance met the obligation target and exceeded the more critical disbursement target. Total program performance in disbursements increased 1.6% over FY 1990.

		PERCENT					
	Allotment	Laboratory		Extramural		Total	
Project	($000)	OBL	DISB	OBL	DISB	OBL	DISB
836	13,205	99	72	100	66	100	67
808	4,840	100	77	100	42	100	64
809	4,460	100	90	97	49	98	65
993	6,445	99	78	100	47	100	56
Total 6.3B	28,950	100	79	99	58	99	64
832	1,010	100	64	100	0	100	63
847	7,875	99	44	100	71	100	66
848	2,645	99	57	99	63	99	62
849	4,678	100	58	100	72	100	65
Total 6.4	16,208	100	55	100	70	100	65
Total Program	45,158	100	70	100	62	100	64

LOGISTICS MANAGEMENT

- Integrated Logistics Support and MANPRINT: The following list of logistical plans and documents were prepared in support of Milestone In-Process Reviews for USAMMDA products this year.

MONTH	TYPE	PRODUCT	DOCUMENT
February	MS I	External Mounted Rescue Hoist	ILSP
October	MS I	Antimicrobial Dermal Dressing	ILSP
October	MS Ib	Multichambered Autoinjector	ILSP
		BOIPFD/QQPRI	

- Other documents prepared in support of the project management offices include:

Project Office	Product	Document
Applied Medical	Resuscitative Fluids Prod. System	Tgt Aud Descr
		Joint ILSP
	Resuscitative Device, Ind. Chem.	Memo of Notif
	Self Contained Ventilator	ILSP
	Field Medical Oxygen Generating	DMSP
	and Distribution System	MFP
		ILSP Update
		BOIPFD/QQPRI
	Liquid Oxygen Production System	Transp Report
		ILSP
		BOIPFD/QQPRI
	X-ray System, Dental, Miniature	Tgt Aud Descr
		MFP
	X-ray System, Lightweight,	BOIPFD/QQPRI
	Medical	ILSP
		NETP
		MFP
	CT Scanner, Field	ILSP Update
		ILSP
	WBGT Monitor	BOIPFD/QQPRI
		BOIPFD/QQPRI
	Medical Filmless Imaging System	BOIPFD/QQPRI
Biological	Arthropod Repellent Clothing Imp.	ILSP/Update
Pharmaceutical	Convulsant Antidote, Nerve Agents	Trans. Plan
	WR 6026	ILSP
	Halofantrine	ILSP
	WR238605	ILSP
	Topical Skin Protectant	ILSP
	Schistosome Topical Antipenetrant	ILSP Update
	Ribavirin, Prophylactic	ILSP

All of the required documentation supporting the project office development programs was prepared within the mandated milestone and DOD guidelines of cost, performance and schedule as it relates to each product.

The logistics data base was updated to reflect all changes in product status resulting from the annual Medical Systems Review Committee (MSRC) Meeting, MAMP and USAMMDA Review and Analyses.

- Project Management Support: The Logistics Management Branch is providing the Contracting Officer's Representative (COR) for Contract DAMD17-85-C-5122, for development of a Field Medical Oxygen Generating and Distribution System (FMOGDS). Branch personnel arranged and participated in the end of the test scoring conference for technical and user testing and a reliability, availability and maintainability assessment conference. As a result of findings during the technical and user testing programs, the conferences recommended comprehensive changes to the system configuration being requested by the government which impacted on the period of performance of the contract as well as the technical aspects of the system development.

- Production Contract Preparation: The contract statement of work and other supporting documents for the initial production contract for the FMOGDS were completely drafted and staffed within USAMRDC and USATROSCOM. All comments received from the staffing of these documents have been received, and the procurement package is 95% complete. The Logistics Management Branch played a major role in the development of the contractual documents for the Full Scale Development and Initial Production of the X-ray System, Dental, Miniature, as well as providing membership and participation in the Source Selection Evaluation Board. Support was also provided to the Pharmaceutical Systems Project Management Division for development of the procurement package for the Multichambered Autoinjector contract.

- Test Schedule and Review Committee Support: The Logistics Management Branch serves as the USAMRDC interface for the AMEDD Test Schedule and Review Committee (TSARC). Membership and participation was provided for the following meetings:

  Army Medical Department TSARC Working Group
  U.S. Army Operational Test and Evaluation Command TSARC Working Group
  U.S. Army Health Services Command Test and Evaluation Ad Hoc Working Group

REGULATORY AFFAIRS

- Protocol Review and Monitoring - Review of clinical protocols prior to implementation and monitoring of OTSG-sponsored clinical studies conducted by DOD facilities and contractors continued throughout the year. Coordination with DOD investigators participating in the multicenter study to increase patient randomization was intensified with a reminder that the studies at DOD sites will be terminated if sufficient patients are not enrolled. A monitoring trip, sponsored by USAMMDA, with the Centers for Disease Control and USAMRIID, reviewed records of the 10 year ongoing Lassa Fever clinical study in Sierra Leone, Africa.

- Regulatory Affairs Contract - The Project Management Support Division is the COR for a Regulatory Affairs support contract. Nineteen task orders were issued during the year. Thirteen were for Biological Systems support, one was for support of the REFLUPS PMA, and the remaining five supported Pharmaceutical Systems efforts. A new category of effort, post marketing surveillance, was added this year for two NDAs sponsored by The Surgeon General.

- Quality Assurance Committee - A Good Clinical Practices (GCP) Course was organized at Fort Detrick in August 1991. As a result of conditions discovered on monitoring visits to various USAMRDC laboratories, attendance at a GCP course is now mandatory for USAMRDC Principal Investigators (PI) using human subjects. The committee also moved to implement written standards for data retention and began the effort with an inventory of data at a contract storage facility.

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APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Applied Medical Systems Project Management Division is a multidisciplinary team with broad mission responsibilities to centrally manage the development and initial production of applied medical products, related diagnostic equipment, vision corrective eyewear products, and pesticide delivery systems.

MILITARY RELEVANCE

Applied Medical Systems is committed to developing compact, lightweight, durable medical equipment to achieve both the Army's demanding Service-unique and multi-Service mission requirements. Diverse, multi-discipline technologies are integrated to create a wide range of state-of-the-art systems. Equipment initiatives are directed toward addressing medical defense against chemical warfare agents, medical protection against military hazards, and the ability to provide care to the combat casualty.

OBJECTIVES

Army readiness is predicated upon the timely and successful execution of programs by the Materiel Developer. To achieve this, Applied Medical Systems capitalizes on emerging Tech Base efforts and aggressively manages the development component of the AMEDD Research, Development and Acquisition process to meet DA and Joint Services performance and supportability requirements for field-survivable medical equipment.

PRODUCT DESCRIPTIONS

- The Field Medical Oxygen Generation and Distribution System (FMOGDS) is an on-site, lightweight medical oxygen generating and distribution system which provides both bedside and cylinder-refill oxygen capabilities within TOE hospitals and medical logistics organizations. The system is designed to provide greater mobility, greater operational flexibility, and reduce logistics dependence on medical grade oxygen resupply.

- The Resuscitative Fluids Production and Reconstitution System (REFLUPS) is a device which produces sterile Water for Injection from a potable water source, combines that water with concentrated electrolytes to formulate parenteral solutions, and packages the solutions in sterile plastic IV bags.

- **Laser Protective Eyewear (Materiel Change)** is a family of polycarbonate eyewear which consists of the spectacle frontsert, helmet visor, spectacle lenses, mask outserts, and eyewrap. These eyewear products are designed to attenuate laser threats (two or three wavelengths) emitted from range finders, target designators, and low energy laser weapons.

- The **Steam Vacuum Pulse Sterilizer System (SVPSS)** is a microcomputer-controlled automatic steam sterilizer which employs a pressure/vacuum pulse-conditioning principle for air removal and is designed to sterilize instruments, linens, and solutions for field hospitals.

- The **Water Quality Analysis Set - Preventive Medicine (WQAS-PM)** will utilize test-strip and drop-count titration technology to determine if field water supplies meet established standards for Arsenic, Cyanide, Chloride, Magnesium, and Sulfate in potable water.

- The **Water Sampling Submission Kit (WSSK)** is a simple-to-use, light-weight set of prepackaged and pretreated containers for collecting and preserving samples of raw and treated water in the field. The WSSK will be tailored for submitting water samples to the Theater Area Medical Laboratory.

- The **Rapid Bacteriological Test Kit (RABTEK)** is an updated field bacteriological test kit to detect and quantify coliforms in water samples within four to six hours. This kit will include coliphage detection technology. The RABTEK will significantly reduce the time required to determine the sanitary quality of potential water sources, and if treated water supplies meet Army bacteriological standards.

- The **Field Computed Tomography Scanner (CT)** is a commercial x-ray computed tomography system which is shock mounted and installed in a 2:1 International Standard Organization Shelter and provides diagnostic quality CT information.

- The **Medical Filmless Imaging System (MFIS)** is the Combat Digital Radiography System which has been renamed to reflect the change in the requirements. The system is aimed at the elimination of film, film processors and chemicals from the field by obtaining the radiographic information in an electrical form.

- The **Miniature Dental X-Ray System (XRSDM)** is a small, lightweight, hand-held dental x-ray system for field use. The system consists of a hand-held x-ray generator subsystem (suitable for use with self-developing film or digital imager)

and a digital imaging and storage subsystem for displaying images without the use of film.

- The **X-Ray System, Lightweight, Medical (XRSLM)** is a battery operated radiographic system which will weigh about one hundred pounds and will produce diagnostic quality 14 x 17 inch images. It is intended to be used in place of the current low capacity system and by the Special Forces.

- The **Self-Contained Ventilator (SCV)** is a Powered Ventilator with the requirements to support levels I and II echelons. It is a lightweight portable device which uses oxygen or filtered ambient air to resuscitate and ventilate casualties in the field combat environment.

- The **Life Detector (LD)** is a hand-held device providing a noninvasive method for detecting heart beat, respiration, or other indicator of the presence of life, through chemical protective clothing without compromise to the protective ensemble or individual.

- **M-40 CB Protective Mask Vision Correction (Materiel Change)** is a vision correction device using the Ballistic Laser Protective Spectacle prescription lens carrier and is internally mounted on the M-40 CB protective mask. Prescription lenses are mounted in the frame component of this eyewear.

- **Prescription Lens Carriers (Materiel Change)** is an optional component of the Ballistic-Laser Protective Spectacles and an integral component of the M40 CB Protective Mask Vision Correction. The carrier holds standard prescription lenses.

- **M43 CB Protective Mask Vision Correction** is a vision correction frontsert (device which externally mounts to the mask). Prescription lenses are mounted in the frame component of this eyewear.

- The **Heat Stress Monitor (HSM)** consists of an Electronic Wet Bulb Globe Temperature Monitor to measure dry bulb temperature, wet bulb temperature, and globe temperature, and a Hand-held, Heat-stress Calculator (HHC). The HHC contains a prediction algorithm capable of computing work and rest cycles and associated water requirements for the individual soldier under a variety of environmental conditions.

- The Computer Assisted Post-Mortem Identification System (CAPMI) consists of computer hardware and a software routine comparing antemortem and postmortem dental records to yield a list of most probable matches for facilitating the process of identifying human remains.

- The Externally Mounted Rescue Hoist (EMRH) will be mounted on UH-60A (Black Hawk) Medical Evacuation (MEDEVAC) helicopters. It will allow 25 to 33 percent more space inside the aircraft compared to the current design with internally mounted rescue hoist. The additional cabin space can be used for patient care, medical equipment, and the MEDEVAC litter kit. Use of the EMRH will decrease mission time required for extraction of casualties or personnel and decrease aircraft weight.

- The Decontaminable Folding Litter (Litter) is capable of being decontaminated and providing a surface on which patients can be Chemical Warfare Agent decontaminated. It consists of aluminum poles and spreader bars, decontaminable mesh fabric and retractable nylon handles.

- The Molecular Sieve Oxygen Generating System (MSOGS) will provide medical grade oxygen on Medical Evacuation aircraft for trauma and chemical agent patient resuscitation.

MAJOR ACCOMPLISHMENTS

- The **Field Medical Oxygen Generating and Distribution System (FMOGDS)** entered Full Scale Development. Extensive technical testing at Dugway Proving Ground, delayed several months because of Operation Desert Storm (ODS), was completed in 4QFY91. User testing was conducted in 2QFY91. Major failures during testing occurred in the compressor unit, software, and cylinder filling. The development contract was extended through 1QFY92 to make and validate corrective design changes to the system. All failures were corrected. The Milestone III In-Process Review (IPR) was rescheduled for 2QFY92.

Liquid oxygen (LOX) technology was also evaluated. Several attempts to test a LOX plant were also delayed by ODS. A test was initiated in 1QFY92 at Fort Sam Houston, Texas. The distribution of LOX to hospitals was demonstrated during ODS with success. Both the FMOGDS and LOX have the potential to meet field medical oxygen requirements.

- Subsequent to the Special IPR for the **Resuscitative Fluids Production and Reconstitution System (RFFLUPS)** held in 1QFY91, an extensive series of additional reviews were conducted within the military Medical Departments and Department of Defense culminating in the recommendation by the Assistant Secretary of Defense (Health Affairs) to continue the development program. The Joint Service Operational Requirement was approved by the U.S. Army Training and Doctrine Command on 1 May 1991. Systems Engineering Testing was completed. Block changes which resulted from testing were implemented in the Engineering Development Models. A Study Plan for Food and Drug Administration approval of the Pre-market Approval Application was completed. Software was integrated with the hardware. Validation of technical manuals was begun. Preparations were made for Reliability, Logistics, and Maintenance Demonstrations, Validation Testing, and the Initial Operational Test and Evaluation.

- Additional quantities of two and three wavelength **Laser Protective Visors** and **Laser Protective Aviator Spectacles**, contracted for in April 1991, were produced and delivered. A laser protective clip-on, for use with standard spectacles, was developed and produced as part of this action.

- In October 1991, the Food and Drug Administration (FDA) approved the 510(k) Pre-market Notification for the **Steam Vacuum Pulse Sterilizer System (SVPSS)**. This FDA finding permits the Army to continue with the SVPSS Production and Initial Deployment Phase.

- A Joint Working Group was held in November that made decisions on the development of the **Water Quality Analysis Set - Preventive Medicine (WQAS-PM)**, **Water Sampling Submission Kit (WSSK)**, and the **Rapid Bacteriological Test Kit (RABTEK)**. Draft Operational Requirements Documents for all three kits were reviewed, Army field water quality standards were verified, and input was provided for modifying each kit's Acquisition Strategy. A Market Investigation on the WQAS-PM, WSSK, and the RABTEK was completed which identified potential manufacturers of each kit. Use of Nondevelopmental Items (NDI) in each kit is feasible.

- Two commercial **Field Computed Tomography Scanner (CT)** systems, shock mounted in International Standard Organization shelters, were deployed in support of Operation Desert Storm. The data gathered is being collated and evaluated, and an after action report will be published. One of the units has been sent to Korea and will undergo cold weather evaluation.

- A Market Investigation for commercial systems or components which will meet the need for a **Medical Filmless Imaging System (MFIS)** was conducted. The results indicate that, although not all of the needs can be met by a currently available commercial product, the technology is available and can be integrated into a useful system.

- A Request for Proposal package for procurement of the **X-Ray System, Dental, Miniature (XRSDM)** was assembled and sent to interested vendors. A source selection board met in December and negotiations are underway.

- Two **X-Ray Systems, Lightweight, Medical (XRSLM)** were assembled. Technical testing was conducted at the University of Wisconsin. Environmental testing is in progress at the U.S. Army Biomedical Research and Development Laboratory. A Safety Assessment is underway, and development of the manuals has begun.

- Seven **Self-Contained Ventilators (SCV)** were obtained from the vendor. These were modified to conform to new requirements (separating echelon Levels I and II usage from Levels III and IV) which were agreed upon in 3QFY91.

- The Heart Motion Sensor prototypes, developed and delivered during 1991, underwent user testing as part of the **Life Detector (LD)** Concept Evaluation Program. The Safety assessment requirement for the Microwave Reflectance prototypes was initiated by the U.S. Army Biomedical Research and Development Laboratory prior to beginning technical testing.

- Technical testing for the **M40 CB Protective Mask Vision Correction (Materiel Change)** was completed. Results indicate superior weapon-compatibility of the new product over the existing metal insert. Production of mounts was initiated.

- Environmentally stable materials were investigated and a new material selected for the **Prescription Lens Carrier**. Testing of new carriers was initiated.

- A Market Investigation for potential manufacturers for the **M43 CB Protective Mask Vision Correction** was conducted.

- Contractual development of the **Heat Stress Monitor (HSM)** began at Southwest Research Institute in August 1991. Preliminary Design Review and Critical Design Review Meetings were held. The development of preliminary software screen displays, definition of user interfaces, evaluation and employment of sensors, and selection of electronic components were completed.

- The **Computer-Assisted Postmortem Identification System (CAPMI)** software was rewritten in ADA language. The Defense Eligibility Enrollment Reporting System (DEERS) conducted a successful pilot study for incorporating the CAPMI antemortem dental data into DEERS.

- An IPR for the **Externally Mounted Rescue Hoist (EMRH)** was conducted in 2QFY91. The recommendation was made to assign the Materiel Developer responsibility for this project to AVSCOM. PM Utility Helicopters at AVSCOM agreed to accept the project upon completion of their reorganization in 2QFY92. Project development efforts were placed on hold pending transfer to AVSCOM. At this time, AVSCOM seems to be in the process of reversing their decision to accept Materiel Developer responsibility for this project.

- Improvements to the **Decontaminable Folding Litter (Litter)** were made as a result of Air Force testing. The original fabric was too smooth and presented a safety hazard during the transport of patients. Different textures of the decontaminable material were examined for increased friction.

- A Draft Required Operational Capability was developed and staffed for the **Molecular Sieve Oxygen Generating System (MSOGS)**. An Abbreviated Analysis was also compiled. The decision was made to assign the Materiel Developer responsibility for this project to AVSCOM. PM Utility Helicopters at AVSCOM agreed to accept the project upon completion of their reorganization in 2QFY92. Project development efforts were placed on hold pending transfer to AVSCOM. At this time, AVSCOM seems to be in the process of reversing their decision to accept Materiel Developer responsibility for this project.

PROJECTIONS

- The **Field Medical Oxygen Generation and Distribution System (FMOGDS)** Milestone III IPR will be held 2QFY92.

- The **Resuscitative Fluids Production and Reconstitution System (REFLUPS)** Army Initial Operational Test and Evaluation will be conducted on three REFLUPS Engineering Development Models in April 1992. The Premarket Approval Application will be submitted to the Food and Drug Administration in May.

- Final deliverables with chemical agent resistant coating for the **Laser Protective Eyewear (Materiel Change)** will be delivered 2QFY92. Contract expiration date is March 1992.

- The **Steam Vacuum Pulse Sterilizer System (SVPSS)** essential characteristics will be finalized in anticipation of a Request for Proposal on a production contract in FY 92. Force Packaging will guide the deliverables under the contract.

- A Request for Proposal for the **Water Quality Analysis Set - Preventive Medicine (WQAS-PM)** will be offered in 2QFY92. A Milestone I IPR for the WQAS-PM will he held in 3QFY92.

- A Milestone I IPR for the **Water Sampling Submission Kit (WSSK)** will be held in 3QFY92. An assembled WSSK prototype tailored for the Theater Area Medical Laboratory will be reviewed for Nondevelopment Item (NDI) fielding by the U.S. Army Medical Materiel Agency.

- The **Rapid Bacteriological Test Kit (RABTKK)** will be developed and packaged as a modified NDI for coliform and coliphage testing.

- The cold weather evaluation of the **Field Computed Tomography Scanners (CT)** will be completed. The data will be evaluated, and a product specification will be developed which is suitable for competitive procurement.

- A product specification for the **Medical Filmless Imaging System (MFIS)** will be developed and a Request for Proposal initiated.

- A contract will be signed for the procurement of the **X-Ray System, Dental, Miniature (XRSDM)** for evaluation with a full scale production option.

- The **X-Ray System, Lightweight, Medical (XRSLM)** will be completed and undergo Concept Evaluation Program testing in August 1992.

- Changes in the power supply of the **Self-Contained Ventilator (SCV)** will solve the problems uncovered in the pre-test evaluation, and the units will undergo Concept Evaluation Program testing in May 1992.

- Based on results of Concept Evaluation Program tests and technical testing of **Life Detector (LD)** prototypes, Heart Motion Sensor and Microwave reflectance devices, a decision to proceed to full scale development with one or both technologies will be made.

- **M40 CB Protective Mask Vision Correction (Materiel Change)** will undergo initial operational tests beginning 2QFY92. Production to support fielding of the M40 mask will continue.

- Production of **Prescription Lens Carriers** to support initial fielding of the M40 mask will be initiated. Technical and user testing of the new material will continue.

- Type classification of the M43 CB mask for aviators will require continued developmental effort for the **M43 CB Protective Mask Vision Correction (Developmental)**. Final design changes will be made during 2QFY92. Test quantities of frontserts will be available by the end of 3QFY92.

- Twenty prototypes of the **Heat Stress Monitor (HSM)** will be delivered to the Army in 3QFY92. Government technical testing will start in 4QFY92. An additional contractual effort will be required to address a completed technical data package for HSM procurement.

- The **Computer-Assisted Postmortem Identification (CAPMI)** project will be transferred to the Health Care System Support Activity for fielding and software maintenance.

- The organization responsible for the development of the **Externally Mounted Rescue Hoist (EMRH)** will be decided in 2QFY92.

- The specification for the **Decontaminable Folding Litter (Litter)** will be revised to reflect the type of material acceptable to the U.S. Air Force.

- The organization responsible for the development of the **Molecular Sieve Oxygen Generating System (MSOGS)** will be decided in 2QFY92.

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BIOLOGICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Biological Systems Project Management Division manages the development and acquisition of biological products to prevent casualties or loss of soldier effectiveness due to disease. These diseases may be naturally acquired by close contact, unsanitary conditions, contaminated environment, biting insects, or acquired by deliberate exposure to aerosols of biological agents including toxins. Product Managers exploit domestic and foreign medical technology to remedy deficiencies identified by the Combat Developer, and monitor research projects for their application to disease protective measures.

MILITARY RELEVANCE

Casualties from disease have been a major cause of hospital admissions and ineffectiveness on the battlefield. Figures for admission for soldiers during a year in Vietnam were as follows: disease - 70.6 percent; battle casualty - 15.6 percent; nonbattle injury - 13.8 percent. Reducing the impact of disease on operations will contribute significantly to soldier effectiveness.

OBJECTIVES

This Division's mission is to develop effective preventive measures against diarrheal diseases, malaria, hepatitis, meningitis, opportunistic wound infections, dengue and Japanese encephalitis, toxins, hemorrhagic fevers, and other diseases spread by aerosol. The mission includes development of rapid methods to identify biological threat agents in clinical samples. Methods to address these deficiencies (some of which include treatment) are vaccines, adjuvants, immune globulins, insect repellents, and rapid identification kits for field use.

PRODUCT DESCRIPTIONS

- Salk Vaccine Production Facility is a manufacturing facility dedicated exclusively to the development and production of vaccines and diagnostic reagents under Federal regulatory guidelines. The facility is managed by a task order contract for scheduling production of vaccines and reagents.

- Johns Hopkins Clinical Testing Facility is a Salk Institute subcontract for testing vaccines produced under sponsorship by the USAMRDC.

- University of Maryland Vaccine Testing Facility is used for evaluating vaccines in human safety and efficacy trials. The trials are done either on hospitalized volunteers, in the 32-bed isolation ward, or on outpatients. Each trial is performed under a specific task order and detailed protocol.

- Vaccinia Immune Globulin (VIG) meets the Department of Defense operational requirement for safe and effective treatment for potential vaccinia complications resulting from experimental vaccinia vectored vaccines, use of standard vaccinia, or offensive use of smallpox virus. The VIG manufacturer will be provided with plasma from hyperimmunized volunteers to ensure a product that exhibits potency criteria required by the Food and Drug Administration for a licensed product.

- Campylobacter Vaccine is a killed, whole cell, adjuvantized oral vaccine for prevention of diarrheal and systemic illness caused by Gram-negative bacteria of the genus Campylobacter. This vaccine is being developed with the U.S. Naval Medical Research Institute.

- Cholera Vaccine is a killed, whole cell and B subunit oral vaccine for prevention of diarrheal and systemic illness caused by Vibrio cholerae infections or by ingestion of cholera toxin. This vaccine is being developed by Phase 2 and Phase 3 evaluation of vaccine purchased for the U.S. Army.

- Rapid Identification System for Biological Agents is a portable, rugged, simple system designed to identify biological agents in clinical materials. In the test, drops of serum from soldiers exhibiting symptoms of disease are placed on credit card sized blotters in plastic holders. After the reagents are added and absorbed, positive or negative results are visible to the unaided eye in less than 30 minutes.

- J-5 Human Monoclonal Antibody reacts with the highly conserved lipid A region of the lipopolysaccharide, binding to a wide variety of endotoxins and Gram-negative bacteria of many genera.

- Klebsiella/Pseudomonas Intravenous Globulin should prevent opportunistic infections in burn and wound patients. The immune globulins obtained from the plasma of volunteers immunized with Klebsiella and Pseudomonas vaccines is tested as

an investigational new drug in patients at Veterans and military hospitals. This is a collaborative effort between WRAIR, Department of Veterans Affairs, and the Swiss Serum and Vaccine Institute.

- Lassa Fever Immune Globulin is prepared under FDA guidelines from the plasma of Lassa fever convalescent patients.

- Hepatitis A Vaccine was produced at WRAIR by growing the virus first in cultured monkey kidney cells and then in human lung cells until antigen concentrations reached a stationary level. The virus was inactivated with formalin, safety tested according to regulatory guidelines, and tested in volunteers. Inactivated vaccines produced by SmithKline Beecham, and Merck, Sharp and Dome, are being tested to determine the most immunogenic product.

- Multivalent Dengue Live Vaccine consists of different serotypes of virus which have been attenuated by passage in primary dog kidney cells at WRAIR. The master and production seeds and the vaccine are produced in fetal rhesus monkey lung cells. Different passage levels of several isolates of the four serotypes will be evaluated in Phase 1 studies. Passage levels which are the most immunogenic with the least amount of reactogenicity for the four isolates will be combined for the multivalent vaccine.

- Vaccinia-Vectored Korean Hemorrhagic Fever (KHF) Vaccine is a live vaccine for military personnel being deployed to locations which are endemic for this agent. The vaccine was developed by inserting the KHF gene that controls the production of immunogenic KHF antigens into a live vaccinia virus carrier (smallpox vaccine). The resulting recombinant vaccine was shown to elicit antibodies against both smallpox and KHF in animals. This vaccine was developed in a collaborative effort between USAMRIID and the Salk Institute.

- Smallpox Live Vaccine is a new, cell culture produced animal poxvirus (vaccinia) that will be free of bacteria presently found in the calf lymph vaccine. This should allow intramuscular rather than percutaneous administration.

- Argentine Hemorrhagic Fever Live Vaccine (AHF) is an attenuated vaccine for military personnel being deployed to endemic areas. The vaccine was prepared by growing the virus in fetal rhesus monkey lung cells in a collaborative effort between USAMRIID and the Salk Institute. Following successful efficacy studies in Argentina, a license application will be prepared.

- **Japanese Encephalitis Vaccine**, extracted from infected mouse tissue by a Japanese company (Biken), has been shown to reduce the incidence of disease in endemic regions of the world. It is currently administered as an investigational vaccine since it is not yet licensed in this country.

- **Chikungunya Live Vaccine** is an attenuated product produced by growing the virus in cultured human lung cells at USAMRIID. The Salk Institute produced the experimental lots of virus vaccine under regulatory guidelines for testing in humans. Following additional human testing, it will be stored in a lyophilized form as a contingency vaccine.

- **Falciparum Malaria Sporozoite Vaccine** is a product of recombinant DNA technology and consists of the circumsporozoite protein of Plasmodium falciparum. The vaccine is produced under a cooperative agreement with SmithKline Beecham Pharmaceuticals. The vaccine is being tested in combination with different types of adjuvants to increase the antibody titers in volunteers.

- **Q Fever CMR Extract Vaccine** is a formalin inactivated vaccine prepared at the Salk Institute from rickettsiae grown in embryonated eggs. Extraction with chloroform-methanol (devised at the USAMRIID) was shown to eliminate severe skin reactions seen in animals inoculated with non-extracted vaccines.

- **Tularemia Live Vaccine** is an attenuated vaccine for military personnel being deployed to an area where there is a potential threat use of Francisella tularensis. New lots of vaccine, prepared at the Salk Institute under slightly modified production protocols, are being tested for safety and immunogenicity in volunteers at the Johns Hopkins University.

- **Botulinal Toxoids (Types ABCDEFG)** will be produced and incorporated into a polyvalent vaccine to protect military personnel. These toxoids will be used for military personnel deployed in areas where there is potential threat use of Clostridium botulinum toxins. To prepare toxoids, the toxins are purified from C. botulinum cultures and inactivated with formalin. Types A and B are being produced currently by standard methods while CDEFG will be concentrated by ultrafiltration and purified by ion exchange chromatography to produce highly purified toxoids. The toxoids will be tested separately and eventually together for their ability to produce toxin neutralizing antibodies in humans.

- **Botulinal F(ab')2 Antitoxin (ABCDEFG) Heptavalent (Equine Derived)** is produced from hyperimmune horse plasma to be used to treat military personnel exhibiting symptoms of clinical botulism. The plasma is treated with silicon dioxide, subjected to pepsin proteolysis and centrifuged to remove aggregates. The F(ab')2 antibody fragments produced are isolated on an ion exchange resin and neutralizing activity is determined against each of the seven toxins by neutralization tests in mice. The lack of the Fc portion of the antibody molecule should result in fewer reactogenicity problems than have been observed with unfractionated horse serum.

- **Shigella Vaccines** are oral products containing live bacteria with specific antigens which should stimulate protective immune responses against diarrheal diseases. These bioengineered vaccines are produced at WRAIR and tested at the University of Maryland Vaccine Testing Facility.

- **N. meningitidis (Group B) Vaccine** is a protein-based vaccine for use in conjunction with licensed polysaccharide vaccines to protect military personnel against epidemic cerebrospinal meningitis. The vaccine is a bacterial sub-capsular protein complexed to polysaccharide antigens. The product is a collaborative effort between WRAIR and Connaught Laboratories and is necessary to protect soldiers against a larger number of strains of this organism.

- **E. coli Polysaccharide Vaccine** is a particulate vaccine composed of E. coli LPS covalently coupled to toxin A. It is designed to prevent infection from wounds and as a vaccine to produce immune plasma for passive treatment of infection.

- **Lipid A Analog Vaccines** are composed of a derivative of gentiobiose heptaacetate, conjugated to a carrier, and induce antibodies against lipid A. The antibodies are expected to be effective against Gram-negative sepsis.

- **Insect/Arthropod Repellent, Clothing Impregnant** is a treatment of permethrin to the Battle Dress Uniform to provide protection from insect/arthropod bites. One treatment lasts for the combat life of the uniform.

- **Insect/Arthropod Repellent Lotion (Materiel Change)** is an improved, controlled release, topically applied insect repellent designed to provide protection from a broader spectrum of disease vectors and pests, especially biting midges and malaria vectors. This effort will focus on selection of the best of three candidate repellent formulations currently being evaluated for efficacy and safety.

• **Body Louse Toxicant** is a 0.5 percent permethrin dust formulation which will replace lindane as the standard pediculicide. The procurement specification will be revised when the formulation is registered.

MAJOR ACCOMPLISHMENTS

• **The Salk Vaccine Production Facility** produced and tested additional lots of chikungunya and Rift Valley fever vaccines. An attenuated Rift Valley fever vaccine was produced and preclinical testing was completed. A pilot lot of Cell Culture Derived Smallpox Vaccine (Vaccinia) was produced and preclinically tested. Master seed, production seed and bulk vaccine lots for a vaccinia-vectored Korean hemorrhagic fever vaccine were prepared and preclinical testing was completed. Pilot lots of dengue 2 were prepared and preclinical testing was completed. As a result of a tasking by the Assistant Secretary of Defense for Health Affairs, the Salk Facility continues to perform tests to extend the shelf life of Vaccinia Immune Globulin (VIG) and, as such, is responsible for receiving, inventorying, storing, potency testing, and shipping this extended date product as directed.

• Under a Salk Institute subcontract, the **Johns Hopkins Clinical Testing Facility** is conducting Phase 1 clinical trials with the Q fever CMR and Tularemia vaccines.

• The **University of Maryland Vaccine Testing Facility** completed a second study of the live E. coli-vectored Shigella flexneri vaccine and another study of milk immunoglobulin concentrate. Extended outpatient studies of antibody responses of volunteers vaccinated simultaneously with Klebsiella and Pseudomonas vaccines continues. A few volunteers received a booster dose; the second dose was well tolerated but responses were not good. This important study will demonstrate whether or not these vaccines should be followed by booster doses. The safety and immunogenicity of an oral adenovirus-vectored hepatitis B vaccine were evaluated and found to be safe but not immunogenic. A number of dengue vaccines were tested on the ward.

• Volunteers were enrolled and efforts begun near five military installations to collect 4500 liters of vaccinia hyperimmune plasma. This plasma will be used by the Hyland Division, Baxter Healthcare Corporation to manufacture **Vaccinia Immune Globulin (VIG)**.

- Whole cell plus B subunit **Cholera Vaccine** was purchased to prevent cholera and enterotoxigenic E. coli infections during Operation Desert Shield/Storm. This product was evaluated in Phase 1 clinical trials at Fort Bragg, North Carolina.

- One thousand kits for each of four agents have been prepared by one of two companies awarded contracts for the **Rapid Identification System**. The kits are currently undergoing technical testing at USAMRIID.

- A military unique IND for **J-5 Human Monoclonal Antibody** was submitted for Operation Desert Storm/Shield. One individual was successfully treated under this IND. The manufacturer, CENTOCOR, has filed a Product License Application with the Food and Drug Administration.

- Ten thousand liters of hyperimmune (Klebsiella/ Pseudomonas) immune plasma were delivered by the contractor and ten lots of **Klebsiella/Pseudomonas Intravenous Immune Globulin** were manufactured by the Swiss Serum and Vaccine Institute. Approximately 1,000 patients were given this intravenous product as part of a multicenter clinical trial at 12 military and Department of Veterans Affairs Hospitals. This study, which must be extended until FY94, is now well established.

- A Phase 3 study was initiated in Thailand with SmithKline Beecham's **Hepatitis A Vaccine**. The vaccine has been shown to be safe and immunogenic. The current study was designed to show efficacy.

- A Cooperative Research and Development Agreement has been signed with Mahidol University, Thailand, to evaluate their **Dengue Vaccines** in Phase 1 studies.

- Several WRAIR **Dengue Vaccines** were evaluated. Dengue 4, Strain 341750, passage 15 was found to be reactogenic. Dengue 1 45AZ5, Dengue 2 S16803 have been found to be non-reactogenic at the passage levels that were evaluated.

- The Salk Institute has completed preclinical testing of the **Vaccinia-Vectored Korean Hemorrhagic Fever Vaccine**.

- Final preclinical tests of a new cell culture derived **Smallpox Live Vaccine** have been completed in monkeys at USAMRIID. A protocol is being drafted for inclusion in an IND submission expected 2QFY92.

- The Phase 3 double-blind field trial of the **Argentine Hemorrhagic Fever Live Vaccine** involving approximately 6500 at-risk Argentine volunteers was evaluated. Due to the largest outbreak of natural disease in several years in the study area, the code was broken. Statistical analysis of the data revealed a vaccine efficacy of 95.5 percent in preventing overt Argentine Hemorrhagic Fever. Final serological data on persistence of antibody will be available in March 1992. During the field trial, no significant vaccine related adverse reactions were noted, and all vaccinees seroconverted.

- Three consecutive lots of **Japanese Encephalitis Vaccine** were tested in humans and serological studies were completed in U.S. soldiers at Schofield Barracks. The results, which demonstrated effective and reproducible immunization, were filed with the Food and Drug Administration as a key element of the Product License Application. An FDA Advisory Committee recommended that the vaccine be licensed.

- Phase 2 studies with the recombinant **Falciparum Malaria Sporozoite** protein covalently bound to Pseudomonas Toxin A are in progress in Kenya and Thailand. FSV2-DETOX vaccine was not protective in challenge studies. Phase 1 studies with hepatitis B/malaria constructs and a malaria non-repeat based vaccine are in progress.

- Independent safety and immunogenicity studies for the **Q Fever CMR Extract Vaccine** are in progress at USAMRIID and at the Johns Hopkins University.

- The Phase 1 clinical trial for **Tularemia Live Vaccine** at USAMRIID has been completed. It was performed as a double blind study involving 30 vaccinees and controls. No unexpected local or systemic vaccine-related reactions were noted. Serological conversions were noted in all volunteers. Additional Phase 1 trials to establish lot consistency (for licensure) have been initiated at the Johns Hopkins University.

- **Botulinal Toxoid Type F**, imported from the Center for Applied Microbiology, Porton Down, U.K., was used to vaccinate horses in support of a U.S. Government effort to produce Botulinal Antitoxin F(ab')2 Antitoxin during Operation Desert Storm/Shield.

- Two vaccine manufacturing suites were renovated at USAMRIID in compliance with current Good Manufacturing Practices to produce **Botulinal Toxoid Type A and B**. The Salk Institute's

Government Services Division is responsible for the manufacture of these toxoids within this new facility.

- **Pentavalent Botulinal Toxoid (ABCDE)** was fielded for use as an Investigational New Drug in Saudi Arabia, and military personnel were vaccinated using an expanded use protocol (IND 3723). The FDA granted a waiver of informed consent for this product during Operation Desert Storm/Shield.

- An Investigational New Drug Application for use of **Botulinal F(ab')2 Antitoxin, Heptavalent (Equine Derived)** was provided to the FDA (IND 3723). USAMRIID completed a Phase 1 safety trial with five volunteers, and the FDA approved the use of this product for treatment of clinical botulism in U.S. service members during Operation Desert Storm/Shield.

- A live, oral, attenuated candidate **Shigella Vaccine** was tested in volunteers. It caused side effects in some volunteers and failed to produce either good immune responses or protection from challenge in most volunteers. New animal data has shown that a 2 week interval between doses confers a stronger immune response. Milk immunoglobulin concentrate with antibody activity against Shigella flexneri 2a was tested in human volunteers. This product protected 100 percent of volunteers against a challenge dose of Shigella flexneri 2a, demonstrating the feasibility of passive immunoprophylaxis of mucosal surfaces.

- Outer membrane vesicle-based **Group B Meningitidis** vaccines prepared from parent strains and a class 4 deficient mutant are presently being manufactured at Connaught Laboratories. Phase 1 studies will begin after the manufacturing testing has been completed and an IND application has been submitted.

- The Phase 1 safety and immunogenicity study of the **E. coli Polysaccharide Vaccine** has enrolled 34 individuals, and 9 of these have received a second immunization. There were no serious reactions, and most volunteers responded to a majority of the antigens.

- Two Investigational New Drug Applications for gentiobiose heptaacetate constructs C-1 and C-6 (**Lipid A**) were submitted to the FDA (INDs 4143 and 4144).

- One factory impregnation and two unit level methods were selected for **Arthropod Repellent Clothing Impregnation** with the repellent permethrin. The Project Manager, Clothing and Individual Equipment has supported the effort to treat the desert BDU at the factory using the pad roll application method and

requested concurrence by the Type Classification Review Panel. Defense General Supply assigned NSNs to the IDA Kit (6840-01-345-0237) and the permethrin application with the compressed air sprayer (6840-01-334-2666).

- The EPA notified the registrant of the **Body Louse Toxicant** malathion of its intent to cancel the registration for use on clothing. Therefore, a decision was made to seek EPA approval for use of a 0.5 percent permethrin dust formulation. Since there is no registration for a permethrin dust used as a pediculicide in the U.S., a market investigation to identify manufacturers who would allow registration of their formulation by the Army was initiated.

PROJECTIONS

- The **Salk Vaccine Production Facility** will produce and evaluate bulk botulinal toxoids A and B at their manufacturing suites in USAMRIID. Neutralization tests will be conducted on samples of botulinal antitoxin produced in horses; further processing for human use will be performed by the University of Minnesota. A new baculovirus expression system for production of Anthrax PA Antigen will be scaled-up at the Salk Swiftwater site to permit production of amounts of antigen sufficient for use in the development of a new, improved vaccine. Plague vaccine may be manufactured at the Swiftwater site if no commercial manufacturers can be located.

- Under a Salk Institute subcontract, clinical trials at the **Johns Hopkins Clinical Testing Facility** will include Phase 1 studies with tularemia, Q fever CMR, EEE, and avipox-vectored rabies vaccines.

- **A Contingency Vaccine Storage Facility** (military) will be completed at the National Center for Toxicological Research, Little Rock, Arkansas. Portions of the Salk Institute vaccine stockpiles will be stored here.

- The **University of Maryland Vaccine Testing Facility** will evaluate the safety and efficacy of *E. coli*/*Shigella flexneri* following vaccination of volunteers with a lower dose of vaccine. A multivalent immune milk immunoglobulin concentrate, with activity against enterotoxigenic *E. coli* and *Shigella sp.*, will be evaluated in volunteers. Dengue vaccine studies will continue and meningococcal vaccines will be tested under Phase 1 protocols.

- Sufficient plasma to manufacture the first production lot of **Vaccinia Immune Globulin (VIG)** is projected to be collected by the end of the first quarter of calendar year 92. Production of the first lot of VIG is projected to begin during the second quarter of calendar year 92.

- The development of an oral, whole cell, adjuvantized **Campylobacter Vaccine** will be initiated. Pilot lots of vaccine will be manufactured and tested in animals during the preclinical phase of development.

- Whole Cell and B Subunit **Cholera Vaccine** will be tested in Phase 2 clinical trials in Peru and Chile. If the vaccine is shown to be safe and immunogenic in volunteers, the vaccine will enter into Phase 3 field trials in South America.

- Concept Evaluation Program testing of the **Rapid Identification System** is scheduled for 4Q92, pending satisfactory technical testing.

- **Klebsiella/Pseudomonas Intravenous Immune Globulin** will be tested for safety and efficacy at Veterans Administration medical centers and military medical centers.

- The IND for **Lassa Fever Immune Globulin** will be submitted and the Phase 1 trial conducted at USAMRIID.

- Two dose efficacy will be determined for the Phase 3 study in Thailand with the SmithKline Beecham killed **Hepatitis A Vaccine**.

- Phase 1 testing of SmithKline Beecham's live-attenuated **Hepatitis A Vaccine** will be completed.

- An IND will be submitted for Phase 1 studies on **Dengue Vaccines** manufactured in Thailand. Phase 1 studies for WRAIR-developed dengue vaccines will continue.

- An IND application for the **Vaccinia-Vectored Korean Hemorrhagic Fever Vaccine** will be prepared and submitted to the FDA in 2QFY92.

- Phase 1 clinical studies will be initiated with the pilot lot of **Vaccinia (Smallpox) Live Vaccine**.

- Manufacturing consistency lot studies will be performed using the **Argentine Hemorrhagic Fever Live Vaccine**.

- The Food and Drug Administration is expected to accept the Advisory Committee recommendation to license the **Japanese Encephalitis Vaccine**.

- As the **Chikungunya Live Vaccine** may interfere with the response to other alphavirus vaccines administered subsequently, it will be administered simultaneously with live Venezuelan equine encephalitis vaccine to determine if antibodies against both will be developed.

- Phase 2 challenge studies of a liposome encapsulated **Falciparum Malaria Sporozoite Vaccine** will be completed.

- Safety and challenge studies (Phase 1 and 2) will be conducted on a new repeatless **Falciparum Malaria Sporozoite Vaccine** encapsulated in liposomes.

- Phase 1 clinical trials for **Q Fever CMR Vaccine** will continue at USAMRIID and Johns Hopkins University. An IND application will be made to compare CMR and whole cell skin test antigens in immune individuals. Results should indicate whether the CMR vaccine will be less reactogenic than the previously used whole cell vaccine in immune individuals.

- Data from the current volunteer study at Johns Hopkins University, designed to obtain **Tularemia Live Vaccine** lot consistency data required for licensure, will be available by 4QFY92. This data and those from earlier studies at USAMRIID will be used to assemble a data package in support of a license application for this vaccine in late 1992.

- An Investigational New Drug Application for **Botulinal Toxoid Type F** will be submitted to the FDA upon completion of safety, sterility, and optimal dose experiments at the Center for Applied Microbiology, Porton Down, U.K. A Phase 1 safety trial conducted at USAMRIID for Botulinal Toxoid Type F Toxoid will begin 3QFY92.

- **Botulinal Type G** toxoid will be produced at the Center for Applied Microbiology Research, Porton Down, U.K. This non-cGMP quality toxoid will be used to vaccinate horses to produce Botulinal F(ab')2 Antitoxin, Heptavalent (Equine Derived).

- The genetically engineered **Shigella flexneri Vaccine** will be evaluated at a lower dose and with a 2 week interval between doses.

- Phase 1 and 2 safety and immunogenicity studies of the **E. coli Polysaccharide vaccine** will continue.

- **A** Phase 1 protocol for gentiobiose heptaacetate C-1 and C-6 (**Lipid A Analog**) under INDs 4143 and 4144 will begin 3QFY92.

- Several formulations of candidate **Improved Extended Duration Topical Arthropod Repellents**, made by the 3-M Company under a CRDA, will be provided for continued laboratory and field efficacy testing by WRAIR and the Navy. Candidate compounds will be evaluated to determine their relative effectiveness when compared to the extended duration Deet formulation, which is the DOD standard issue repellent.

- Fairfield American Corporation is expected to agree to collaborate with the Army regarding EPA registration of a permethrin dust formulation that can be used as a **Body Louse Toxicant**.

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PHARMACEUTICAL SYSTEMS PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Pharmaceutical Systems Project Management Division centrally manages the development and the initial production of pharmaceutical systems (antidotes and drugs), related drug delivery systems (autoinjectors and transdermal patches), resuscitative fluids, skin protectants and decontaminating products. These products are fielded as preventive, protective and therapeutic modalities for use against chemical and biological warfare threats, certain endemic diseases and the treatment of combat casualties.

MILITARY RELEVANCE

U.S. military forces must be prepared to serve anywhere in the world against any threat. This could result not only in conventional injuries sustained during combat operations but exposure to chemical and biological warfare agents as well as exposure to endemic diseases not commonly found in the United States. The development of products against these threats will help save lives, sustain the fighting force and enhance return to duty.

OBJECTIVE

The objective of this Division is to develop pharmaceuticals to be used for prophylaxis, immediate treatment and definitive treatment against a wide variety of naturally occurring diseases, threat force use of chemical and biological agents and combat injuries. These pharmaceuticals include those for use following exposure to organophosphorus compounds, vesicants and cyanide, and those to protect or treat soldiers suffering from malaria, schistosomiasis and leishmaniasis. In addition, a topical skin protectant is undergoing development to protect the skin against the toxic effects of exposure to mustard and other percutaneous chemical threat agents. From a more conventional aspect, blood replacement fluids and improved antimicrobial skin dressings and microencapsulated antibiotics are under development.

PRODUCT DESCRIPTIONS

- **Hypertonic Saline Dextran (HSD)** is a safe and effective small-volume resuscitative fluid suitable for rapid field administration that can be used to stabilize hypovolemic shock casualties. A Collaborative Research and Development Agreement (CRDA) is established with Kabi-Pharmacia for the development of this product.

- **WR 6026** is an 8-aminoquinoline methanol derivative being tested as an oral treatment for visceral leishmaniasis.

- **WR 238605** is an 8-aminoquinoline derivative currently in the Demonstration/Validation Phase of development as an antimalarial drug. It is being developed as a replacement for primaquine for the prophylaxis and treatment of Plasmodium vivax malaria.

- **Halofantrine** is a 9-phenanthrenemethanol antimalarial compound that is being jointly developed by the USAMRDC and SmithKline Beecham as an alternative treatment for use in mefloquine resistant Plasmodium falciparum malaria.

- The **Schistosome Topical Antipenetrant (TAP)** is a niclosamide-based skin lotion that is designed to prevent the penetration of free swimming schistosomal larva. A CRDA has been established with Miles Pharmaceuticals, Inc., for the formulation and manufacture of this lotion for clinical studies.

- The **Antimicrobial Dermal Dressing (ADD)** will be capable of providing sustained release of antimicrobial agents at the site of superficial dermal injury to prevent infection, enhance healing and protect against the external environment.

- The **Multichambered Autoinjector (MA)** is a single-barreled, dual-chambered autoinjector which injects the nerve agent antidotes, atropine and pralidoxime chloride through a single needle.

- The **Topical Skin Protectant (TSP)** is a perfluoroalkylpolyether compound which, when spread on the skin, forms a lasting, thin and breathable film surface capable of complete or significant protection, for a certain duration, against percutaneous penetration of chemical warfare agents. Use of the TSP enhances the effectiveness of fielded skin decontaminating systems. Doctrine for use of TSP is as an adjunct to mission-oriented protective posture gear, not as a replacement.

- The **Microencapsulated Antibiotic, Ampicillin (MEAA), Dental** is an antibiotic delivery system designed for single dose, direct wound site application by dental personnel at the time of debridement of maxillofacial injuries. It is capable of maintaining antibiotic concentrations at high levels at the wound site while producing systemic concentrations that are much lower than with conventional treatments.

- **HI-6**, a Hagdorn oxime, is a nerve agent antidote under development as a replacement for pralidoxime chloride, a component of the Mark I Nerve Agent Antidote Kit. Animal data indicate that HI-6 offers greater protection against soman and a wider range of threats than does pralidoxime. Because of stability problems associated with HI-6 when in solution, a wet-dry multichambered autoinjector, using atropine in the "wet" chamber is envisioned.

- **Ribavirin, Postexposure Prophylactic** is a synthetic nucleoside, under development as an oral postexposure prophylactic against viral hemorrhagic fever diseases. It is intended primarily for high risk personnel (physicians, nurses, etc.) who have had direct contact with patients diagnosed as having a viral hemorrhagic fever.

- The **Convulsant Antidote for Nerve Agents (CANA)** is a diazepam 10 mg autoinjector intended to prevent or abate convulsions and prevent or reduce brain injury associated with nerve agent poisoning. The CANA is a soldier carried item to be used by buddy-aid in conjunction with the Mark I Nerve Agent Antidote Kit.

- **Arteether** is a sesquiterpenelactone produced by the extraction and purification of the substance artemisian from the plant Artemisia annua. This rapid acting blood schizonticide is being developed for the treatment of cerebral malaria.

MAJOR ACCOMPLISHMENTS

- The CRDA with Kabi-Pharmacia for the development of HSD was extended until 1993. The Food and Drug Administration (FDA) continued their review of the New Drug Application (NDA) which was submitted in September 1990.

- The initial Phase II clinical trial in Kenya, on WR 6026, was completed. Based on the information obtained, a follow-on Phase II study was initiated to evaluate longer dosing periods.

- An Investigational New Drug Application (IND) was filed with the FDA for WR 238605.

- A one year toxicology study with **Halofantrine** was completed. This was a required study for the prophylactic indication.

- A Phase II/III clinical trial was initiated on **TAP** in the Nile Delta of Egypt in June. Planning continued for two additional clinical trials, one in Brazil and the other in the Upper Nile. A Test Integration Working Group (TIWG) was held on 17 October.

- A Milestone Ia IPR was held for the **ADD** on 16 October. The recommendations were to continue in Concept Exploration and Definition and to maintain an aggressive technology watch.

- A Milestone Ib IPR was held on 16 October for the **MA**. This product was transitioned to the Demonstration and Validation Phase. A final report was received on the Phase I study that was conducted in October 1990 comparing two competing MAs to the Mark I.

- A TIWG was held for **TSP** on 17 October to review the Draft Test and Evaluation Master Plan (TEMP). Critical studies on formulation improvement began in October; an optimized formulation could result in significant unit cost reduction and enhance user acceptability.

- **MRAA** was transitioned to advanced development in March 1990. A Draft Operational and Organizational (O&O) Plan was staffed. An evaluation was conducted of all available data to determine whether an IND was appropriate or if additional studies needed to be conducted. A Market Investigation (MI) was initiated in November. An Acquisition Strategy (AS) was prepared.

- **HI-6** transitioned to advanced development in March 1991. An AS was prepared. An MI was initiated in August.

- The **Ribavirin, Postexposure Prophylaxis** program was cancelled because of the termination of the antiviral program at the USAMRIID.

- During Operation Desert Storm, over 600,000 **CANAs** were delivered to the field.

- **Arteether** was returned to the tech base for additional research.

PROJECTIONS

- The FDA will provide guidance on the NDA application for **HSD** 1Q92. Appropriate changes will be made, and the NDA will be resubmitted 4Q92.

- A Phase II/III clinical trial on **WR 6026** will continue. A CRDA will be signed with a development partner 2Q92.

- Phase I clinical studies will be conducted on **WR 238605** 2Q92. A CRDA development partner will be identified 2Q92. Phase II clinical trial protocol preparation will begin 4Q92.

- An NDA will be filed with the FDA for **Halofantrine, Treatment** 1Q92.

- A two year animal toxicology study for **Halofantrine, prophylactic** will be completed 4Q92.

- Phase II/III clinical trials on **Schistosome Topical Antipenetrant** will begin 1Q92 in Brazil. An additional Phase II/III study will begin in Egypt 2Q92.

- ConvaTec/Squibb, CRDA partner, will file a 510K with the FDA for an **Antimicrobial Dermal Dressing** (double antibiotic).

- A contract will be awarded 4Q92 for the final development of the **Multichambered Autoinjector**. Initial planning for an Initial Evaluation Test and Evaluation (IOT&E) scheduled for 4Q94 will begin.

- An optimized formulation for a **Topical Skin Protectant** will be available 1Q92. A pre-IND meeting with the FDA will be held 1Q92. A Milestone I IPR will be held 4Q92. A Request for Proposal (RFP) for Engineering and Manufacturing Development will be prepared by 4Q92.

- An expert dental panel will convene to define user demand and clinical indications for the **Microencapsulated Antibiotic, Ampicillin, Dental** 1Q92. An Acquisition Strategy will be developed 1Q92.

- Additional required toxicological studies will be initiated for **HI-6** 1Q92. A Market Investigation will be completed in 1Q92.

- The final summary report of the Lassa Fever data on **Ribavirin, Postexposure Prophylactic** will be completed 1Q92.

- The production of **Convulsant Antidote for Nerve Agents** under the development contract option is scheduled for 3Q92.

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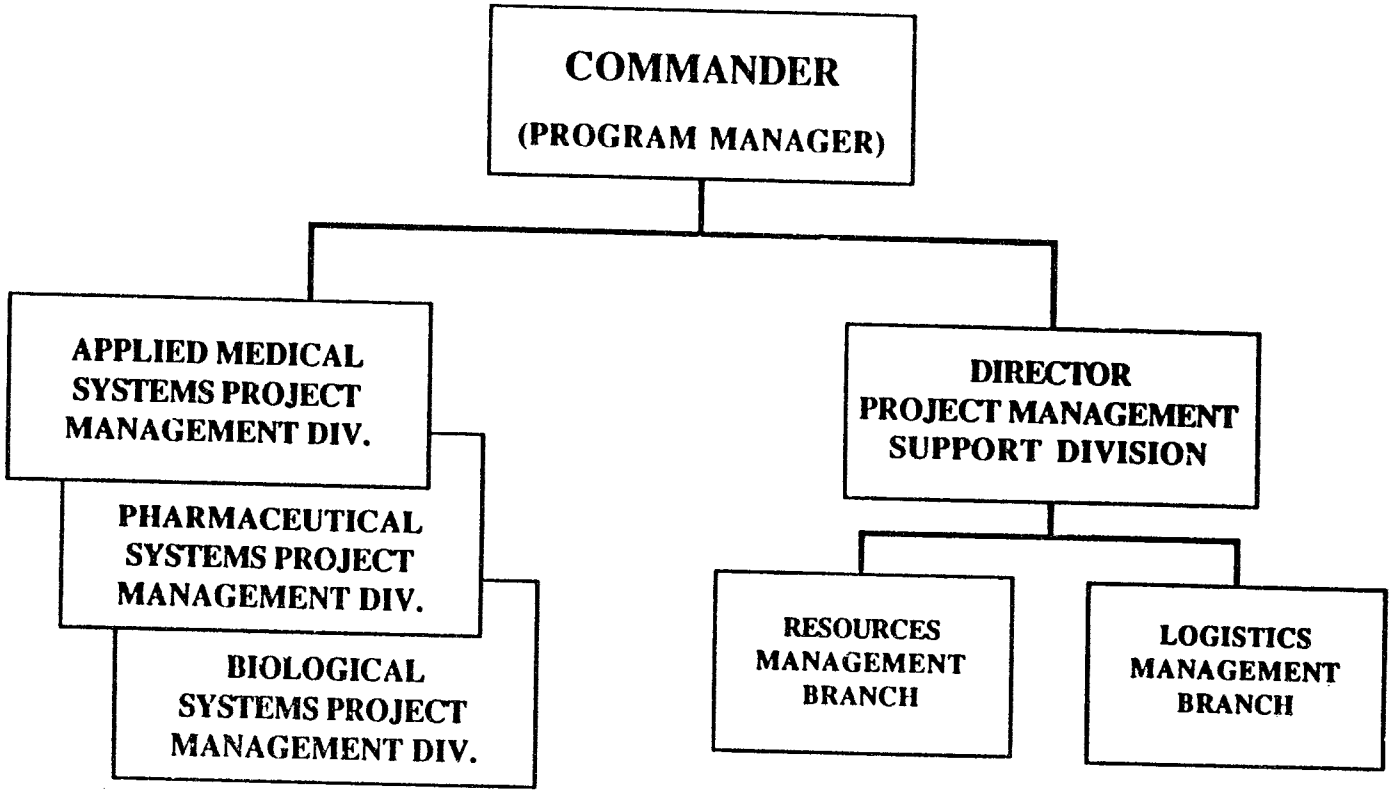
U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY ORGANIZATION



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1991 MEDICAL RDA MAMP PRIORITIZATION

PRODUCT	1991 AMEDD PRIORITY
Field Medical Oxygen Generating and Distribution System	1
Powered Ventilator	2
Hypertonic Saline Dextran	3
Resuscitative Fluids Production System (REFLUPS)	4
Litter, Folding, Decontaminable	5
Antileishmanial Drug, WR6026	6
Antimalarial Drug, WR238605	7
Whole Cell Plus B Subunit Cholera Vaccine	8
Plasmodium Falciparum Sporozoite Vaccine	9
X-ray System, Dental, Miniature (Hand-held Dental X-ray Subsystem)	10
Antimalarial Drug, Halofantrine Prophylactic	11
Hepatitis A, Live Vaccine	12
Hepatitis A Vaccine	13
Botulinal Immune Globulin (Human)	14
Shigella Vaccines	15
Lipid A Analog Vaccine	16
Immune Enhancers	17
X-ray System, Lightweight, Medical	18
Plasmodium Vivax Sporozoite Vaccine	19
Botulism F(AB')2 Antitoxin Heptavalent (Equine Derived)	20
TNF Monoclonal Antibody	21
J-5 Human Monoclonal Antibody	22
Schistosome Topical Antipenetrant	23
Medical Filmless Imaging System (MFIS)	24
N. Meningitis, Group B Protein, Vaccine	25
Arthropod Repellent Extended Duration Formula (MC)	26
Life Detector	27
Tularemia Live Vaccine	28
Multivalent Dengue Vaccine	29
Antimicrobial Dermal Dressing	30
Botulinal Polyvalent Toxoid	31
Lassa Fever Immune Globulin	32
Klebsiella/Pseudomonas Intravenous Immune Globulin	33
Aerosol Generator, Ultra Low Volume, Electric (AGULVE)	34
External Rescue Hoist, UH-60	35
Chikungunya Live Vaccine	36
Vaccinia Vectored Korean Hemorrhagic Fever Vaccine	37
Q-Fever CMR Extract Vaccine	38
Rapid Bacteriological Test Kit (RABTEK)	39
E. Coli Polysaccharide Vaccine	40
Molecular Sieve Oxygen Generating System	41
Filmless Dental Imager (FDI) [P3I]	42
Cell Culture Derived Smallpox Vaccine (Vaccinia)	43
Campylobacter Vaccine	44
Multichambered Autoinjector (MA)	45
Sprayer, Pesticide, Electric, Liquid	46

1991 MEDICAL RDA MAMP PRIORITIZATION

PRODUCT	1991 AMEDD PRIORITY
Argentine Hemorrhagic Fever Live Vaccine	47
Korean Hemorrhagic Fever Vaccine	48
Rapid Identification System	49
CT Scanner, Field	50
Rift Valley Fever Live Vaccine	51
Topical Skin Protectant	52
Microencapsulated Antibiotic, Ampicillin, Dental	53
Water Quality Analysis Set - Preventive Medicine (WQAS-PM)	54
Environmental Health Monitor	55
Water Sampling Submission Kit (WSSK)	56
Nerve Agent Antidote, HI-6	57
Ribavirin, Post-exposure Prophylactic	58
M-40 Chemical-Biological Protective Mask Vision Correction (MC)	59
Computer-assisted Postmortem Identification (CAPMI) System	60
Computer-assisted Postmortem Identification (CAPMI) [P3I]	61
Laser Protective Eyewear (MC)	62

1990 USAMMDA INTERNAL (Z) PRIORITIZATION

Product	Z Priority
USAMMDA Administration and Management	0.01
Task Order Contract	0.02
Salk Vaccine Production Facility	0.03
Vaccine Testing Facility, University of Maryland	0.04
Regulatory Affairs	0.05
Toxicology, Hazleton	0.06
Phase I Clinical Pharmacology Studies	0.07
Toxicology, University of Illinois	0.08
Configuration Management, Medical Materiel	0.09
Configuration Management, Pest Control Equipment	0.10
Formulation	0.11
Medical Research and Evaluation Facility (MREF)	0.12
SRI (Drug Stability Studies)	0.13
Field Eval. of Drugs Against Infectious Disease of Mil Import.	0.14
Clinical Investigations	0.15
Maintenance Contract for UH-60SFTSS	0.16
Field Medical Oxygen Generation and Distribution System	1.00
Resuscitative Fluids Production System (REFLUPS)	2.00
Convulsant Antidote for Nerve Agents (CANA)	3.00
Topical, Skin Protectant	4.00
Nerve Agent Pre-Treatment Pyridostigmine	5.00
Hypertonic Saline Dextran	6.00
Klebsiella/Pseudomonas Intravenous Immune Globulin	7.00
Multichambered Autoinjector (MA)	8.00
Laser Protective Eyewear (MC)	9.00
Hepatitis A Vaccine	10.00
Self-Contained Ventilator	11.00
Shigella Vaccines	12.00
Resuscitation Device, Individual, Chemical	13.00
Sterilizer, Steam Vacuum Pulse	14.00
Rapid Identification System	15.00
Botulinal Polyvalent Toxoid	16.00
Cell Culture Derived Smallpox Vaccine (Vaccinia)	17.00
Antimalarial Drug, WR238605	18.00
Antimalarial Drug, Halofantrine Treatment	19.00
Antimalarial Drug, Halofantrine Prophylactic	20.00
M-40 Chemical-Biological Protective Mask Vision Correction (MC)	21.00
Litter, Folding, Decontaminable	22.00
Life Detector	23.00
Molecular Sieve Oxygen Generating System	24.00
X-Ray System, Dental, Miniature (Hand-Held Dental X-Ray Subsystem)	25.00
External Rescue Hoist, UH-60	26.00
Tularemia Live Vaccine	27.00
Arthropod Repellent Extended Duration Formula (MC)	28.00

Product	Z Priority
Schistosome Topical Antipenetrant	29.00
Japanese Encephalitis Vaccine	30.00
Plasmodium Falciparum Sporozoite Vaccine	31.00
Multivalent Dengue Vaccine	32.00
Q-Fever CMR Extract Vaccine	33.00
N. Meningitis, Group B Protein, Vaccine	34.00
X-ray System, Lightweight, Medical	35.00
Arthropod Repellent Clothing Impregnant	36.00
J-5 Human Monoclonal Antibody	37.00
Adenovirus-Vectored Hepatitis B Vaccine	38.00
Vaccinia Vectored Korean Hemorrhagic Fever Vaccine	39.00
Hepatitis A, Live Vaccine	40.00
Antileishmanial Drug, WR6026	41.00
Antimalarial Drug, Arteether	42.00
Antidote, Nerve Agent, 2nd Generation	43.00
Plasmodium Vivax Sporozoite Vaccine	44.00
Korean Hemorrhagic Fever Vaccine	45.00
E Coli Polysaccharide Vaccine	46.00
Heat Stress Monitor	47.00
Aerosol Generator, Ultra Low Volume, Electric (AGULVE)	49.00
Sprayer, Pesticide, Electric, Liquid	50.00
Monitor, Vital Signs, NBC Casualty	51.00
Vaccinia Vectored Venezuelan Equine Encephalitis Vaccine	52.00
Computer-Assisted Post-Mortem Identification System	53.00
Water Quality Analysis Set - Preventive Medicine (WQAS-PM)	54.00
Rapid Bacteriological Test Kit (RABTEK)	55.00
Water Sampling Submission Kit (WSSK)	56.00
Antimicrobial Dermal Dressing	57.00
Antileishmanial Drug, Pentostam	58.00
CT Scanner, Field	59.00
Ribavirin, Therapeutic	61.00
Microencapsulated Antibiotic, Ampicillin, Dental	63.00
Medical Aerosolized Nerve Agent Antidote (MANAA)	64.00
Pesticide Dispersal Unit, Multicap., Helicopter Slung	65.00
Digital Imaging Network System (DINS)	66.00
Combat Emergency Medicine Expert System	67.00
Lightweight Intravenous Fluids Production System (IV Fluid Maker)	68.00
Draw Over Anesthesia Apparatus	69.00
Chikungunya Live Vaccine	70.00
Argentine Hemorrhagic Fever Live Vaccine	71.00
Lassa Fever Immune Globulin	72.00
Rift Valley Fever Live Vaccine	73.00
Lipid A Analog Vaccine	74.00
TNF Monoclonal Antibody	75.00
Campylobacter Vaccine	76.00
Plasmodium Falciparum, Blood Stage Vaccine	77.00
Anthrax Recombinant DNA Vaccine	79.00

Product	Z Priority
Staph Enterotoxin B	81.00
ION Channel Blocking Toxin (SAXITOXIN) Vaccine	83.00
Post-Synaptic Toxin Vaccine	84.00
Pre-Synaptic Toxin Vaccine	85.00
Medical Filmless Imaging System (MFIS)	88.00
Antimalarial Drug, Mefloquine	89.00
Immune Enhancers	90.00
Filmless Dental Imager (FDI) (P31)	93.00
Skin Decontaminating Kit: M291	95.00
Ballistic-Laser Protective Spectacles (B-LPS)	96.00
Patient Wrap, CWA Protective	97.00
Morphine Repackaging	98.00
Botulinal Immune Globulin (Human)	99.00
Sterilizer, Special Operations Forces (SOF)	100.00
Dengue Recombinant DNA Vaccine	107.00
Rift Valley Fever Vaccine	110.00
Body Louse Toxicant Powder	111.00
Arthropod Repellent Topical Extended Duration Formulation	112.00
Refrigerator, Medical Field	113.00
Dental Operation Unit, Field	114.00
Computer-Assisted Postmortem Identification (CAPMI) (P31)	116.00
Nerve Agent Antidote, HI-6	117.00
Botulism F(AB')2 Antitoxin Heptavalent (Equine Derived)	118.00
Microencapsulated Antibiotic, Cephalosporin	119.00
Intravenous Access Device	120.00
Archival Storage	121.00
Retrovirus Vaccine, GP160	122.00
Retrovirus Vaccine, GP120	123.00
Retrovirus Vaccine	124.00
Anti-Retrovirus Drugs	125.00
Retrovirus Diagnostic System	126.00
AZT Follow-on Trials	127.00
Enterotoxigenic E. Coli Vaccine	128.00
Whole Cell Plus B Subunit Cholera Vaccine	129.00
Ribavirin, Post-Exposure Prophylactic	130.00